

Message

From: Herrick, Jacquelyn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40DA8860B1DD43D9B006AC1E0E9E04CE-MARCHESE, J]
Sent: 8/6/2021 12:01:40 PM
To: Dingle, Hester [Dingle.Hester@epa.gov]
Subject: RE: PM Review Requested: 8329-RRI (D#567067); R300; Due 8/6
Attachments: 8329-118-20210806.pdf

To the gatekeeper!

Ex. 5 Deliberative Process (DP)

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Dingle, Hester <Dingle.Hester@epa.gov>
Sent: Thursday, August 05, 2021 4:31 PM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: PM Review Requested: 8329-RRI (D#567067); R300; Due 8/6

Hey Jackie,

Attached is all the things for EPA Reg. No. 8329-RRI (Decision #567067) and R300 due tomorrow. This is for a new product claiming to be similar to EPA Reg. No. 1021-1688. Right now there was that PFAS issue identified by PC and all the ID shenanigans. In the letter I highlighted the area where you will want to look over. Additionally, I haven't heard back if the registrant wants to move the statement that is under Environmental Hazards to Use Restrictions but I know you said it would be fine for now.

1. Updated label (I have it named Final Label) redlined
2. Updated label unmarked (called Final 8329-RRI.. R300)
3. Revised DM dated 6/2/21
4. Updated Data Citation 3/11/21
5. PC Review
6. Tox Review
7. Reg Letter-
8. Rates calculations
9. Me too label 1021-1688

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From assignment email:

8329-RRI R300, D#567067, due 5/7/21. This product was initially submitted incorrectly and I went back and forth with the registrant on the correct PRIA code. They revised a bunch of their documents to qualify for the R300. In that time the PRIA had to get renegotiated and then the product only passed the 21 day screen a few weeks ago, so now it needs to get renegotiated again.

1. Please bean PC studies, CSF and me-too CSF to PC.
2. Bean tox studies, CSF and me-too CSF to tox.

3. Find the me-too data matrix, make sure the efficacy studies match, the rates on the labels and the claims on the label match, and an efficacy review will not be needed. **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

4. The attached emails includes updated documents that you wont find in documentum, and documentation for the first renegotiation. Please include these emails in the record and use the documents in the emails for the beans. Please provide these to the reviewer (revised label and data matrix too).
5. Please conduct a label review. Make sure the rates and claims match the me-too. Also make sure the technical source(s) of active ingredient is labeled for the use.

From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Sent: Thursday, August 5, 2021 3:33 PM

To: Dingle, Hester <Dingle.Hester@epa.gov>

Subject: RE: 8329-RRI (D#567067); R300; Due 8/6

Hi Hester,

Ex. 5 Deliberative Process (DP)

Thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
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(703) 347-0559
herrick.jacquelyn@epa.gov

From: Dingle, Hester <Dingle.Hester@epa.gov>

Sent: Thursday, August 05, 2021 3:22 PM

To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Subject: FW: 8329-RRI (D#567067); R300; Due 8/6

Hey Jackie,

Just two questions with the revised label:

- 1.
2. **Ex. 5 Deliberative Process (DP)**

I attached the most recent label (8329-RRI Anvil... redline..HD) and the revision comments they sent back (UPDATED LABEL...).

Thanks,
Hester

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Thursday, August 5, 2021 1:48 PM
To: Dingle, Hester <Dingle.Hester@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Cc: Karen Larson <klarson@clarke.com>
Subject: RE: 8329-RRI (D#567067); R300; Due 8/6

Hello Hester,

Thank you for getting back to me on that statement. I've attached a revised label and a readlined version. There were a few changes from what you had requested. I added comments explaining why we made the changes we did. If you need more information, or would like to discuss it further, please let me know.

Sincerely,

Leisha Schumacher
Senior Regulatory Specialist
675 Sidwell Ct. | St. Charles, IL 60174
Phone: 630-671-3152
Email: lschumacher@clarke.com



From: Dingle, Hester <Dingle.Hester@epa.gov>
Sent: Thursday, August 5, 2021 8:45 AM
To: Leisha Schumacher <lschumacher@clarke.com>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Cc: Karen Larson <klarson@clarke.com>
Subject: RE: 8329-RRI (D#567067); R300; Due 8/6

Good morning Leisha and Karen,

Jackie and I did some digging and the glove comment is supposed to be there. I've attached the Tox review and then if you look on page 141 of the [Label Review Manual](#) it has it there as well.

Let me know if you have any questions or need anything else. Also, if you cannot get the label comments done today, please send them to Jackie and CC me tomorrow. Tomorrow is my off day.

Thanks,
Hester

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Wednesday, August 4, 2021 2:29 PM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Cc: Dingle, Hester <Dingle.Hester@epa.gov>; Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Karen Larson <klarson@clarke.com>
Subject: RE: 8329-RRI (D#567067); R300; Due 8/6

Hello Jackie,

Thank you for getting back to me. I appreciate the opportunity to discuss this further. I would also like to include Karen

Larson on the call. We are available tomorrow morning from 9-9:30 (8-8:30 central).

Thank you,

Leisha Schumacher

Senior Regulatory Specialist

675 Sidwell Ct. | St. Charles, IL 60174

Phone: 630-671-3152

Email: lschumacher@clarke.com



From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Sent: Wednesday, August 4, 2021 12:46 PM

To: Leisha Schumacher <lschumacher@clarke.com>

Cc: Dingle, Hester <Dingle.Hester@epa.gov>; Saunders, Jennifer <Saunders.Jennifer@epa.gov>

Subject: RE: 8329-RRI (D#567067); R300; Due 8/6

Hi Leisha,

I had a meeting about your label and these wide-area mosquito products in general with PRD this morning. Would you be willing to have a quick chat about the ID issue tomorrow morning? We have 9-9:30 and 10:30-11 available. Let us know if you'd be willing to discuss this matter further and if any of these times work.

Thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Leisha Schumacher <lschumacher@clarke.com>

Sent: Wednesday, August 04, 2021 12:01 PM

To: Dingle, Hester <Dingle.Hester@epa.gov>

Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Subject: RE: 8329-RRI (D#567067); R300; Due 8/6

Hello Hester,

Thank you for your comments. Some of the changes are simple, and others are more complex. I've attached a PDF responding to your comments. If you open your comments, you should be able to see my replies. If that does not work, please let me know.

I did have a question for one of the changes. For the change in the User Safety Recommendations box about gloves, could you please point me to where this language comes from? It is not on any of our other labels or any of the ID tables.

A lot of the replies have to with the ID. We had brought up the sections you pointed out with several of the pyrethroid PRD reviewers back in January. I've attached the email chain we had with them, and the example label that

we sent to them. They confirmed the label format, which is the same layout that we used for the Anvil 4.5+4.5 ULV label. It matches what we proposed for our other labels and what some other registrants proposed. Please let me know the outcome of your conversations with PRD since we are receiving conflicting information.

Sincerely,

Leisha Schumacher

Senior Regulatory Specialist

675 Sidwell Ct. | St. Charles, IL 60174

Phone: 630-671-3152

Email: lschumacher@clarke.com



From: Dingle, Hester <Dingle.Hester@epa.gov>

Sent: Tuesday, August 3, 2021 1:52 PM

To: Leisha Schumacher <lschumacher@clarke.com>

Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Subject: RE: 8329-RRR (D#567067); R300; Due 8/6

Good afternoon Leisha,

A few things to touch base on:

1. I've attached label comments for 8329-RRR (Decision #567067). We recognize some of these recommendations are outside of the scope of the ID. We're working with PRD right now to see if we can get some of the label language in the ID revised for these mosquito abatement products.
2. I am still waiting on the Product Chemistry review to be finished but hoping that it'll be in time for the PRIA due date of Friday.

Let me know if you have any questions.

Thanks,
Hester

From: Dingle, Hester

Sent: Wednesday, June 2, 2021 11:54 AM

To: Leisha Schumacher <lschumacher@clarke.com>

Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Subject: RE: 8329-RRR Renegotiation Request

Good morning Leisha,

Thanks for the quick response. I'll be in touch if I need anything else in the meantime.

Let me know if you need anything as well.

Thanks,
Hester

From: Leisha Schumacher <lschumacher@clarke.com>

Sent: Wednesday, June 2, 2021 10:34 AM

To: Dingle, Hester <Dingle.Hester@epa.gov>

Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Subject: RE: 8329-RRI Renegotiation Request

Good morning Hester,

Attached to this email is a revised set of Data Matrixes (Agency and Public), which now includes the addition of MRID 46770001 for the two guidelines.

Thank you for the time you spend reviewing the documents for this submission. If you need anything else, please let me know.

Sincerely,

Leisha Schumacher

Senior Regulatory Specialist

675 Sidwell Ct. | St. Charles, IL 60174

Phone: 630-671-3152

Email: lschumacher@clarke.com



From: Leisha Schumacher

Sent: Tuesday, June 1, 2021 2:19 PM

To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Dingle, Hester <Dingle.Hester@epa.gov>

Subject: RE: 8329-RRI Renegotiation Request

Thank you Jackie and Hester,

I am glad you clarified. I wasn't sure if knowing why it was removed would change anything, and I figured it would help to have more information. I appreciate you working with me to make sure it's correct. I'll send a revised version this week with the addition of MIRD 46770001. If you think of anything else in the mean time, please let me know.

Sincerely,

Leisha Schumacher

Senior Regulatory Specialist

675 Sidwell Ct. | St. Charles, IL 60174

Phone: 630-671-3152

Email: lschumacher@clarke.com



From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Sent: Tuesday, June 1, 2021 11:55 AM

To: Leisha Schumacher <lschumacher@clarke.com>

Cc: Dingle, Hester <Dingle.Hester@epa.gov>

Subject: RE: 8329-RRI Renegotiation Request

Hi Leisha

In order to fall within the R300 PRIA code, your application needs to cite the same efficacy studies on the data matrix. The request for a revised data matrix a few months ago was because I was helping you fit your application into this code. The MRID Hester pointed to is a generic magnitude of residue study, it does not support efficacy of your product but rather provides information on the active ingredient when it is applied over ag fields and comes in contact with certain crops.

Many thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Tuesday, June 01, 2021 12:32 PM
To: Dingle, Hester <Dingle.Hester@epa.gov>
Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RRI Renegotiation Request

Hello Hester,

Back in January I was asked to correct the data matrix for 8329-RRI to cite the same studies as the me-too product. MIRDS 48253401 and 46770001 were initially cited on the data matrix for 8329-RRI, but were not on the matrix for the primary product. With that in mind, I removed the two MRIDs starting with the data matrix dated 03/11/21, which is why they are not on the most recent version dated 05/19/21.

It would be nice to have some clarity on if it is needed or not. I'm sure both of us would prefer to have fewer versions of the data matrix. That said, if it needs to be on there, just let me know and I will send you a revised version. If you have any other changes, please let me know and I will incorporate them.

Sincerely,

Leisha Schumacher
Senior Regulatory Specialist
675 Sidwell Ct. | St. Charles, IL 60174
Phone: 630-671-3152
Email: lschumacher@clarke.com

From: Dingle, Hester <Dingle.Hester@epa.gov>
Sent: Tuesday, June 1, 2021 9:45 AM
To: Leisha Schumacher <lschumacher@clarke.com>
Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RRI Renegotiation Request

Good morning Leisha,

I was going through some of the documents with this action 8329-RRI (Decision #567067) and realized that on MGK's Letter of Authorization there is an MRID 46770001 for Guideline 860.1000/860.1500 for Magnitude of Residue in Raw Ag. This MRID is not on the current data matrix for 8329-RRI and I wondered if there is a reason why it isn't? If not, could you add it and resubmit the revised data matrix to include that particular MRID.

Hope you enjoyed the long weekend.

Thanks,
Hester

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Wednesday, May 19, 2021 5:22 PM
To: Dingle, Hester <Dingle.Hester@epa.gov>
Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RRI Renegotiation Request

Hello Hester,

I recently submitted a product specific Storage Stability/Corrosion Characteristics study for Anvil 4.5+4.5 ULV (8329-RRI) through CDX. Clarke received feedback from EPA that the argument to bridge the Storage Stability and Corrosion Characteristics data (guidelines 830.6317 and 830.6320) for the substantially similar product [Multicide Mosquito Adulticiding Concentrate 2705 (EPA Reg. 1021-1688)] to a different product with lower concentration of active ingredients was unacceptable. Based on this feedback, we conducted a product specific study with Anvil 4.5+4.5 ULV in the new container. This submission removed the bridged study from the data matrix, and replaced it with the MRID for the product specific study. A revised certificate with respect to data citation is included with the submission.

Here is the receipt confirmation through CDX:

Your PSP package (Anvil Rev) for Clarke Mosquito Control Products, Inc. (8329) has been successfully transmitted to OPP.

Below are the application(s) included in this package and their tracking number(s):
Anvil 4.5 Revision: CDX_2021_005333

Company Name: Clarke Mosquito Control Products, Inc.
Company Number: 8329

If you have any questions, or need anything, please let me know.

Sincerely,

Leisha Schumacher
Senior Regulatory Specialist
675 Sidwell Ct. | St. Charles, IL 60174
Phone: 630-671-3152
Email: lschumacher@clarke.com



From: Leisha Schumacher
Sent: Tuesday, May 4, 2021 3:51 PM

To: Dingle, Hester <Dingle.Hester@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RRI Renegotiation Request

Hello Hester,

This was a hard decision, but we know the Agency has a lot of priorities right now.

Clarke agrees to the renegotiated PRIA Due Date of 08/06/2021 for the application for 8329-RRI.

Sincerely,

Leisha Schumacher

Senior Regulatory Specialist

675 Sidwell Ct. | St. Charles, IL 60174

Phone: 630-671-3152

Email: lschumacher@clarke.com



From: Dingle, Hester <Dingle.Hester@epa.gov>

Sent: Wednesday, April 28, 2021 9:27 AM

To: Leisha Schumacher <lschumacher@clarke.com>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Subject: RE: 8329-RRI Renegotiation Request

Good morning Leisha,

Thank you for getting back to us so quickly. For the renegotiation date, would a 90-day renegotiation date work for you? The current PRIA date is 5/7/21, 90 days would be around Friday, August 6, 2021. Does that work for you?

I'll be in touch if I have any other questions or need anything else.

Thanks,
Hester

From: Leisha Schumacher <lschumacher@clarke.com>

Sent: Wednesday, April 28, 2021 9:49 AM

To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Cc: Dingle, Hester <Dingle.Hester@epa.gov>

Subject: RE: 8329-RRI Renegotiation Request

Good morning Jackie,

Thank you for reaching out. We anticipated that the deadline would be extended. This product is also bridging to a handful of MRIDs that we submitted for the new container evaluation, so we will be watching what is done for similar products to see what might need to be done for this one.

We usually call and leave a voicemail with any passwords. I had not written it down, but after a few tries I figured it out. The password is Ex. 6 Personal Privacy (PP)

If you need anything else, please let me know.

Sincerely,

Leisha Schumacher

Senior Regulatory Specialist

675 Sidwell Ct. | St. Charles, IL 60174

Phone: 630-671-3152

Email: lschumacher@clarke.com



From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Sent: Wednesday, April 28, 2021 5:41 AM

To: Leisha Schumacher <lschumacher@clarke.com>

Cc: Dingle, Hester <Dingle.Hester@epa.gov>

Subject: RE: 8329-RRI Renegotiation Request

Hi Leisha,

Can you provide the password for the EPA version of the data matrix you sent over in March? My apologies if you already sent it, I just went through all of my Clarke emails and couldn't locate it.

I've Cc'ed Hester on this email, she's the reviewer assigned to this application. Just as a warning, she'll be reaching out to you soon to request another renegotiation. In addition to the recode, this application was caught up in the 21 day screen backlog and only made it through a few weeks ago.

Many thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Leisha Schumacher <lschumacher@clarke.com>

Sent: Thursday, March 11, 2021 4:57 PM

To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>

Subject: RE: 8329-RRI Renegotiation Request

Hello Jackie,

Thank you for having some flexibility with the timeline, we appreciate it.

The following documents are attached:

- EPA Form 8570-34/ Certificate to Data Citation
- EPA Form 8570- 35/ Data Matrix, Public
- EPA Form 8570-35/ Data Matrix, Agency Use Only (I will call you with the password)
- Proposed product labeling
- Proposed product labeling with changes noted (redlined)
- d-Phenothrin (Sumithrin) Registration Review Label Table with label changes noted

If you need anything else, please let me know.

Have a good night,

Leisha Schumacher (Abel)
Senior Regulatory Specialist
label@clarke.com
630-671-3152
675 Sidwell Court
St. Charles, IL 60174



From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: March 11, 2021 1:30 PM
To: Leisha Schumacher <lschumacher@clarke.com>
Subject: RE: 8329-RRI Renegotiation Request

Hi Leisha,

Let's move forward with 5/7/21 date, the 8th is a Saturday. Regarding the next steps you outlined below, please submit the revised documents that support the R300 ASAP. When revising the label, please also include the ID changes as proposed.

Thank you,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Thursday, March 11, 2021 11:07 AM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RRI Renegotiation Request

Good morning Jackie,

Would you be willing to an extension to 5/8/21?

So that you can accurately assess the timeline, I want to provide you with an update of all the pending items for this product. By the end of the week, I will have the following documents to you:

- A revised data matrix that removes MRIDs 48253401 and 46770001, and add the MRIDs that were recently submitted for the referenced me-too product (51436401, 51436402, 51498201)
- A revised data citation form to match the date on the revised matrix
- A revised label to remove the additional claims. **Since the registration review label table has been released since this was submitted, would you prefer I add those changes in now?**

Sincerely,

Leisha Schumacher (Abel)
Senior Regulatory Specialist
label@clarke.com
630-671-3152
675 Sidwell Court
St. Charles, IL 60174



From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: March 11, 2021 7:11 AM
To: Leisha Schumacher <lschumacher@clarke.com>
Subject: RE: 8329-RRI Renegotiation Request

Hi Leisha,

After all of the back and forth with this application, we do need to request a PRIA extension. Would Clarke be willing to extend the date 90 days to 6/8/21 for application 8329-RRI?

Also, have all of the updated studies for the new containers been submitted for this application?

Please let me know.

Thank you,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Herrick, Jacquelyn
Sent: Thursday, February 18, 2021 2:31 PM
To: Leisha Schumacher <lschumacher@clarke.com>
Cc: Yanchulis, Michael <Yanchulis.Michael@epa.gov>
Subject: RE: 8329-RRI Recode Needed

Hi Leisha,

Yes, this application can be recoded to the initial code. As no additional fee is required, I do not think the PRIA code will restart again.

Mick, sorry for the back and forth on this one, but can 83529-RRI get recoded to the R300? They have submitted a revised label that no longer requires an efficacy review.

Many thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
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(703) 347-0559
herrick.jacquelyn@epa.gov

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Thursday, February 18, 2021 10:16 AM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RRI Recode Needed

Hello Jackie,

I hope all is well; there is much going on these days! I was wondering if we could discuss this submission. It currently needs a revised data matrix, revised label, and the submission of an additional storage and stability/corrosion characteristics study. Would it be possible to put it back to the original PRIA category with no additional fee if Clarke agrees to an extension that would essentially be the same as restarting the PRIA clock? If a phone call works better for you to go over details or to figure out a different submission path, please let me know.

Sincerely,

Leisha Schumacher (Abel)
Senior Regulatory Specialist
label@clarke.com
630-671-3152
675 Sidwell Court
St. Charles, IL 60174



From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: January 21, 2021 9:46 AM
To: Leisha Schumacher <lschumacher@clarke.com>
Subject: RE: 8329-RRI Recode Needed

Hi Leisha,

My apologies for the delay. I'm still waiting on some guidance from my colleagues on this one. Hopefully I'll have more information next week.

Thanks,

Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Thursday, January 14, 2021 12:41 PM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RRI Recode Needed

Hello Jackie,

Have you had the opportunity to discuss or decide how you would like to receive the revised label and data matrix (ex: in CDX or password protected in an email), and what changes this has on the PRIA code/review?

Thank you,

Leisha Schumacher (Abel)
Senior Regulatory Specialist
label@clarke.com
630-671-3152
675 Sidwell Court
St. Charles, IL 60174



From: Leisha Schumacher
Sent: January 6, 2021 9:23 AM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RRI Recode Needed

Hello Jackie,

I would remove MRIDs 48253401 and 46770001.

Sincerely,

Leisha Schumacher (Abel)
Senior Regulatory Specialist
label@clarke.com
630-671-3152
675 Sidwell Court
St. Charles, IL 60174



From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: January 6, 2021 6:16 AM
To: Leisha Schumacher <lschumacher@clarke.com>
Subject: RE: 8329-RRI Recode Needed

Hi Leisha,

Thanks for your response. Out of curiosity, which MRIDs have you identified? Also, I'd like to ask a few people on my end on how this resubmission should work. I've never had a package recoded twice. I should have an answer for you by the end of the week.

Thanks again,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Tuesday, January 05, 2021 5:38 PM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RR1 Recode Needed

Hello Jackie,

I determined the one efficacy study and one residue study that were included on the matrix submitted for this product that are not on the cited product's matrix. I will send an updated matrix and complete label tomorrow. Do you have a preference between a password protected document through email or the CDX portal?

Sincerely,

Leisha Schumacher (Abel)
Senior Regulatory Specialist
label@clarke.com
630-671-3152
675 Sidwell Court
St. Charles, IL 60174



From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: January 5, 2021 9:01 AM
To: Leisha Schumacher <lschumacher@clarke.com>
Subject: RE: 8329-RR1 Recode Needed

Hi Leisha,

Thanks for the email. Removing that label language would help, however, you have not cited the same exact studies as the me-too therefore an efficacy review would still be triggered. You may change to a cite-all or cite the exact same studies to get out of the R310.

Thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559

herrick.jacquelyn@epa.gov

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Monday, January 04, 2021 6:05 PM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: 8329-RR1 Recode Needed

Hello Jackie,

We were not expecting this to need a different PRIA code, and I think I found the error. This submission has a label that has incorrect claims on it; they were typos/carry overs from an old draft. Are these claims what is causing the recode? We want to remove them since they were there on error. I apologize for any confusion this has caused.

ANVIL® 4.5+4.5 ULV

[An Oil Soluble Synergized Pyrethroid for Quick Knockdown and Kill control of Adult Mosquitoes (Including Organophosphate Resistant Species) (Midges) (and) (Black Flies) in Outdoor Residential and Recreational Areas.]

[For Use Outdoors to (Knockdown and Kill Adult Mosquitoes) in Residential and Recreational Areas.]

[For Use Outdoors (in) [via] Ground Application (Equipment) to (Knockdown and Kill) (Adult Mosquitoes,) (Stable Flies,) (Non-Biting Midges,) (and) (Non-Biting Flies) in Residential and Recreational Areas.]

[Also] [For use (outdoors) (to kill) (in killing) Horn Flies and Biting Midges (via) (in) (through) Ground Application (Equipment).]

[For (use in) Aerial or Ground Application (Equipment) to Knockdown and Kill Adult Mosquitoes.]

Sincerely,

Leisha Schumacher (Abel)
Senior Regulatory Specialist
label@clarke.com
630-671-3152
675 Sidwell Court
St. Charles, IL 60174



From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: December 30, 2020 6:57 PM
To: Yanchulis, Michael <Yanchulis.Michael@epa.gov>
Cc: Leisha Schumacher <lschumacher@clarke.com>
Subject: RE: 8329-RR1 Recode Needed

Thank you Mick

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1

Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Yanchulis, Michael <Yanchulis.Michael@epa.gov>
Sent: Wednesday, December 30, 2020 7:16 PM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Cc: 'label@clarke.com' <label@clarke.com>
Subject: RE: 8329-RRR Recode Needed

Hi Jackie,

I have recoded this application per your request. The recoding letter is attached requesting an additional payment of \$3,003.

*Mick Yanchulis
Information Services Branch
Office of Pesticide Programs, U.S. EPA*

From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: Monday, December 14, 2020 1:54 PM
To: Yanchulis, Michael <Yanchulis.Michael@epa.gov>
Subject: 8329-RRR Recode Needed

Hi Mick,

The PRIA code for 8329-RRR is currently set at an R300. Unfortunately, an efficacy review will be needed for this one because there are public health pests on the label and the studies don't match the me-too product. Therefore, can you please recode this to an R310?

Let me know if you have any questions.

Thanks,
Jackie

Jacquelyn Herrick, PM 3
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